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DEVELOPMENT OF VIBROCARDIO-
GRAPHIC INSTRUMENTATION

Contract NASw-923
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NORTH AMERICAN AVIATION, INC.
SPACE and INFORMATION SYSTEMS DIVISION



FOREWORD

This document presents the final technical report of Contract NASw-923, "Development of Vibrocardiographic Instrumentation." Prepared by the Space and Information Systems Division (S&ID) of North American Aviation, Inc. This report is submitted to the Office of Advanced Research and Technology (Code RBB), National Aeronautics and Space Administration, Washington, D. C., 20546.



ABSTRACT

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A program for the development and qualitative analysis of a myocardiographic sensor as a means of evaluating vibrocardiographic data is discussed. The report describes the design, fabrication, and surgical implantation of these myocardiographic strain gauge sensors. Postimplant recordings, including left ventricular pressure and electrocardiogram, were taken over a 30-day period. Although the sensor responds to activity of the myocardium over the small area under the sensor, the data obtained indicate that more generalized ventricular activity also can be assessed, especially that related to ventricular volume. The myocardiograph appears to offer a new tool for assessing myocardial activity.



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INTRODUCTION

The advent of space flight has emphasized the need for new and improved techniques for physiological monitoring. Of primary importance is the retrieval of data on the effects of acceleration and weightlessness upon man. Until man achieves the goal of long-duration space flight, however, the animal subject remains as a logical source for the derivation of valuable data on these effects.

One critical problem involving use of the animal as an experimental tool—that of maintaining sensor attachment to the animal—can be remedied by implanting sensors within the animal. Not only does this technique alleviate the problem, but it can also provide data not obtainable from the human subject, such as recordings of continuously monitored blood pressure or myocardial activity.

The program for the development and qualitative analysis of an implantable myocardiographic sensor—the subject of this report—has emerged as an answer to the need for new and improved physiological monitoring. At program outset, the approach to the monitoring of myocardial activity was through the implantation of semiconductor strain gauges bonded to stainless steel arches.

This report describes the design, fabrication, and implantation of a strain gauge sensor system to produce myocardiograms. A qualitative analysis of the data was obtained and limited conclusions were drawn.



DEVELOPMENT OF MYOCARDIOGRAPHIC SENSOR SYSTEM

This portion of the program involved the design, fabrication, and testing of a myocardiographic strain gauge sensor suitable for chronic attachment to the hearts of canines. To accomplish this objective, general and specific design goals were established.

DESIGN CONSIDERATIONS

General Goals

Several design considerations were set forth as a guide throughout the program—namely, the sensor configuration should be biologically acceptable, not interfere noticeably with the normal well-being of 9- to 23-kilogram canines for 30 days or more, and the sensor assembly should include a transcutaneous connector to provide a permanently exteriorized electrical connection to facilitate postimplant recording.

Specific Goals

Sensor Configuration

A design resembling an "arch" with two suturing tabs was selected for the strain gauge mounting plate with nominal dimensions of 3/16-inch height by 1/4-inch width by 3/4-inch length. The basic metal details were to be fabricated of corrosion-resistant, stainless steel processed to meet the anticipated cyclic life.

Cyclic Life

It was determined that the sensor should be designed to function for 1,000,000 cycles to satisfy the goal of a minimum 30-day design.



Biological Interface

The following materials were selected for their biological acceptability and physical properties:

1. Polyurethane for sensor encapsulation¹
2. Polyethylene insulation for electrical leads
3. Plexiglas for the transcutaneous connector.²

Electrical Characteristics

The electrical characteristics chosen are as follows:

1. Power—power requirement of six volts was selected as a safety consideration in case of accidental shortage after implantation. This voltage was to provide a signal of sufficient amplitude to permit remote recording without resorting to buffer amplifiers.
2. Strain gauges—semiconductor, silicon strain gauges with a resistance of 500 ohms ± 15 percent were selected for the anticipated changes of resistance.
3. Redundancy—two silicon semiconductor strain gauges, each with a separate pair of electrical conductors, were to be installed on each metal arch to enhance the reliability of each sensor.
4. Electrical conductors—an NAA designed, polyethylene-insulated, 16-strand, 28-gauge electrical cable was to be used for the electrical conductors. This cable was designed for (1) minimum moisture absorption, (2) maximum mechanical flexibility and resiliency properties, and (3) minimum diameter. All electrical conductors used in sensor fabrication were to be capable of passing a wet dielectric test.

SENSOR ASSEMBLY FABRICATION

The sensor assemblies (Figures 1 and 2) were constructed in several steps, as follows.

¹"Recording Physiological Functions from Unrestrained Dogs," Bio-telemetry, Pergamon Press (1963), pp 303-309.

²Intra-arterial Blood Pressure Sensing System Feasibility Study. Space Systems Division, Air Force Systems Command, Technical Documentary Report 62-59 (1962).

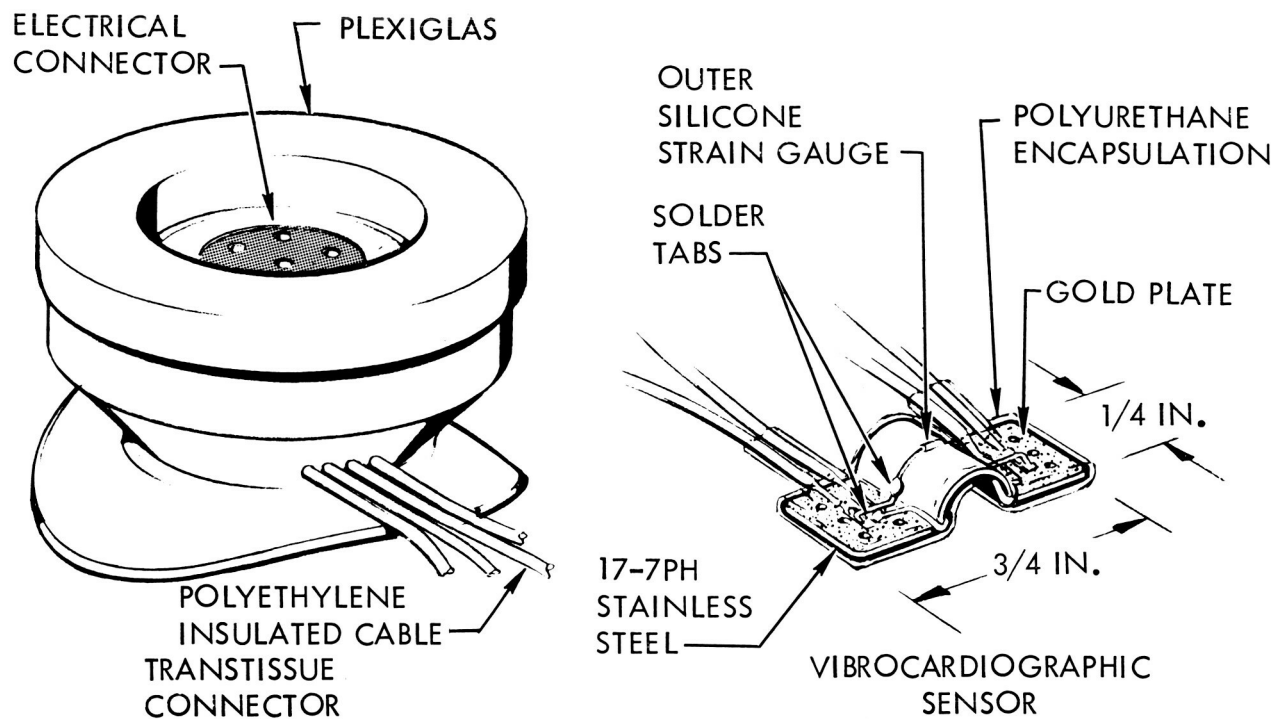


Figure 1. Perspective of Typical Myocardiographic Strain Gauge Sensor Assembly

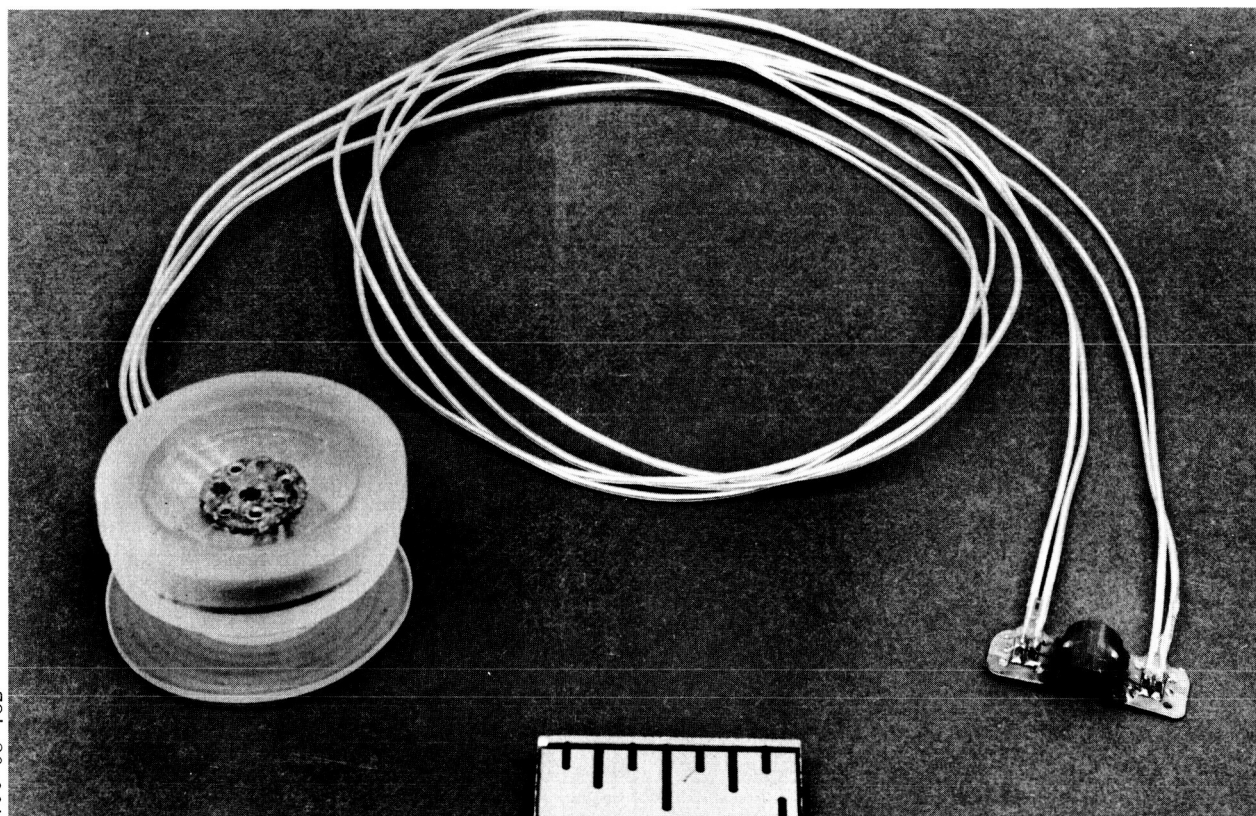


Figure 2. Typical Myocardiographic Strain Gauge Sensor Assembly



Metal Details

The sensors' metal arches were formed from 0.002- and 0.004-inch by 0.250-inch 17-7 PH, condition "C" stainless steel. After the parts were formed, suture holes were drilled in the tabs, and the parts were heat-treated in an argon atmosphere and aged to provide a tensile strength of 180,000 to 200,000 psi. Electroplating was applied to the tabs—copper, 0.002-inch to 0.003-inch, followed by gold, 0.0001-inch—to reduce suture abrasion.

Strain Gauges and Electrical Conductors

Two silicon strain gauges (P/N 110001-001, with a resistance of 500 ohms ± 15 percent, Micro Systems, Inc.) with appropriate intermediate conductors and solder tabs were bonded (No. 6203, Epoxylite Corporation)—one each to the outer and the inner surfaces of the arch—by Micro Systems Inc. In addition, this manufacturer connected and cemented two pairs of polyethylene-insulated electrical conductors (P/N 3006-28-16-PE, Calmot Wire and Cable) to the sensor—one pair to each strain gauge. The ends of the polyethylene-insulated conductors, attached to the sensor, were roughened with sandpaper before attachment to enhance their adhesive bond.

Assembly Encapsulation

The entire sensor assembly, including the sanded insulation on the electrical conductors, was cleaned by wiping with trichlorethylene. A two-part, clear polyurethane primer (CS 9937, Chem-Seal Corporation of America) was applied to the cleaned area. When tack-free, the sensors were dipped in two-part, clear polyurethane (CS 3502, Chem-Seal Corporation of America). This material was mixed, heated, and degassed according to the manufacturer's recommendations. After dipping, the parts were cured for six hours at a temperature of 180 degrees F.

Transcutaneous Connectors

Transcutaneous connectors were machined from clear Plexiglas (Rohm and Hass) bar stock. After machining, the flange to underly the skin was heated and curved for anatomical conformity. Holes were drilled through the connector wall adjacent to the subcutaneous flange to permit passage of the electrical conductors into each connector. A four-pin (female) electrical connector was fabricated by modifying a standard seven-pin socket (M7S, Winchester or equivalent). The electrical conductors were passed through the holes in the connector and soldered to the electrical sockets. Polyurethane primer (CS 9937) was applied to the mating surfaces of the transcutaneous connector, electrical socket, soldered joints, and sanded



insulation of the electrical conductors, which would remain within the transcutaneous connector. Polyurethane (CS 3502) was then used to pot the electrical connector. The flange around the upper perimeter of the transcutaneous connector was sized to accept a plastic, snap-on cap.

SENSOR CALIBRATION

Data on calibration of the myocardiographic sensors were obtained after encapsulation. This was accomplished by suspending the sensors from a suture hole on one tab and hanging weights from a suture hole of the opposite tab to change resistance by approximately 10 percent beyond the design operating range, to determine linearity. Resistance changes were measured on an impedance bridge (Model 250D, Electro-Scientific Instrument, Inc.) at room temperature (78 degrees F). The nominal resistance of each sensor was also measured at 95, 101, and 110 degrees F. to obtain calibration information at higher operating temperatures. Figure 3 presents the calibration plots for the sensors that were eventually implanted.

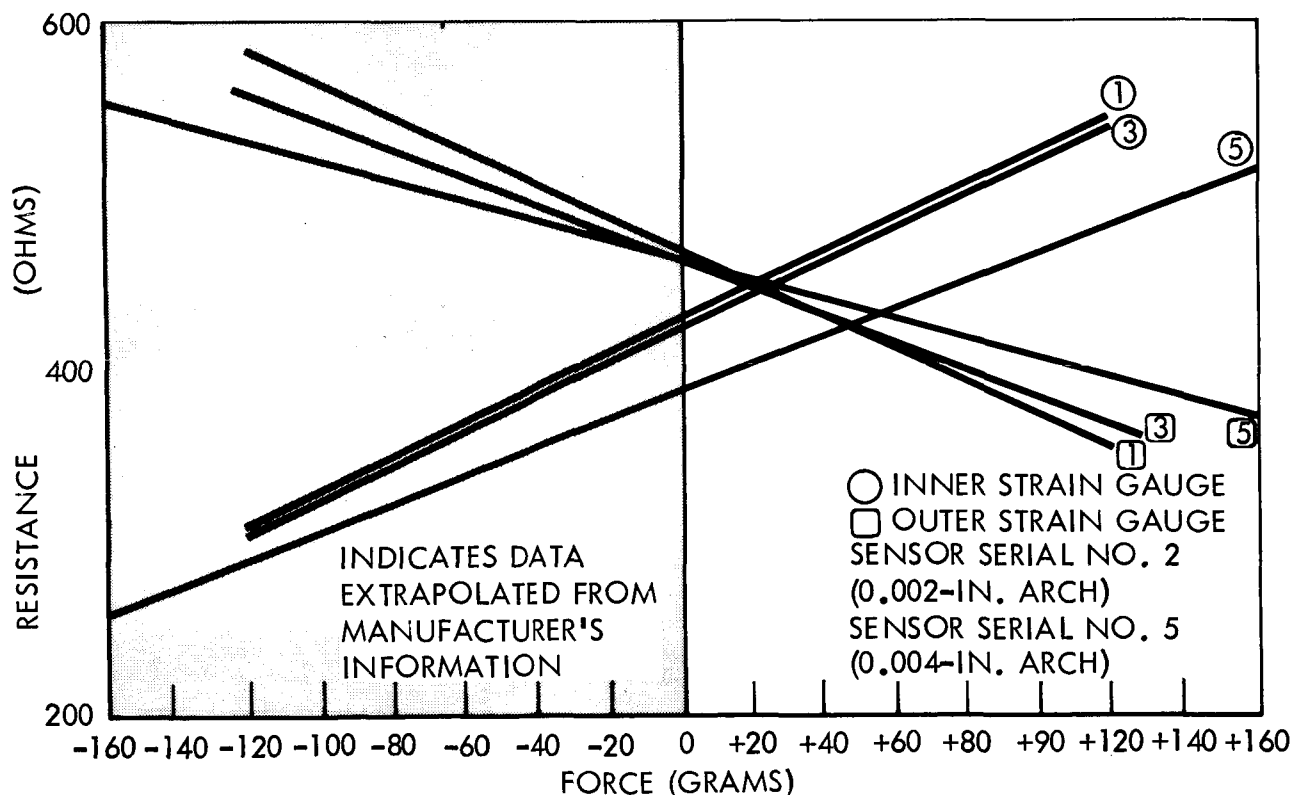


Figure 3. Postencapsulation Data for Myocardiographic Strain Gauge Sensors Used in Surgical Implants



AUXILIARY EQUIPMENT

Conversion of the mechanical activity of the sensor strain gauges to electrical energy was achieved by constructing a bridge-balance box containing three parallel 6 V D-C bridges. This unit facilitated the monitoring of each gauge element and their summed activity. A meter and bridge-balancing controls were included to permit sensor calibration (Figure 4).

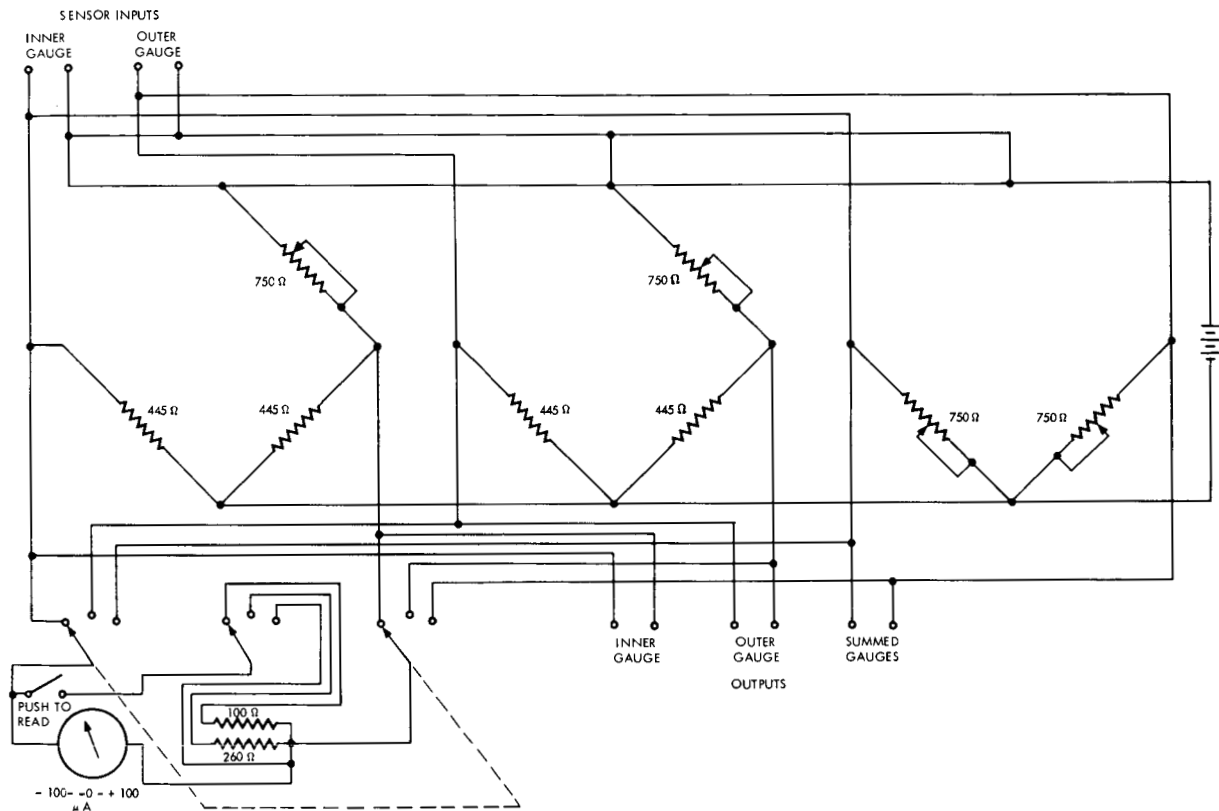


Figure 4. Schematic Diagram of Balanced-Bridge Circuit

Fixed resistors were selected to match the nominal (i.e., unstressed) preimplant resistance value of each strain gauge at 101 degrees F. These resistors were used to balance the bridges during calibration of the recording apparatus.



EXPERIMENTAL PROCEDURES

SUBJECTS

Four male, mongrel dogs weighing approximately 9 to 13 kilograms were selected for this experiment. Prior to surgery, these animals were inoculated, vaccinated, isolated, and observed for two to three weeks. They were washed and treated against vermin one day before surgery. Postoperatively, their diet was Prescription Diet (trademark) dog food and water ad lib.

SENSORS

The sensor assemblies implanted in the four animals were of identical configuration except for the thickness of the stainless steel arches. A 0.004-inch arch was used in the first, second, and fourth animals (Dogs 5165-1, -2, and -4), and a 0.002-inch arch was implanted in the third animal.

Before implantation, each sensor assembly was sterilized in gaseous ethylene oxide for 24 to 48 hours at ambient pressure and temperature, followed by aeration for a minimum of 24 hours.

SURGICAL TECHNIQUES

Exploratory Implants

Before the chronic implants, surgical technique was established with two nonsterile exploratory surgeries involving the implantation of dummy sensors on the surface of the hearts of dogs.

Chronic Implants

Four chronic implant surgeries were accomplished during this program. Procedures and techniques varied slightly for the four animals, as described below.

Anesthesia was accomplished with intravenous and/or intraperitoneal sodium pentobarbital at a level of 27 to 28 mg/kg of body weight. Nitrous oxide was used occasionally during surgery, as required. After the dogs were anesthetized, the hair over their left rib cages was removed and the



skin was prepared with a Phisohex (Winthrop Laboratories, Inc.) scrub rinse, and final wash with benzalkonium chloride. Each animal was then placed on the operating table and draped with sterile linen. An incision was made along the fifth rib on the left, from the sternum to the midaxillary line. Approximately 8-centimeter lengths of the fourth and/or fifth ribs were then resected, while carefully preserving the pleura. The pleura was incised and the pericardial sac was opened. Avoiding the left coronary artery, the sensor was affixed to the myocardium, its long axis in a transverse position. Attachment was made on the ventral aspect near the apex, using four sutures (5/0 Mersilene—Ethicon, Inc.)—two through each mounting tab, except for Dog 5165-1, for which three sutures per tab were used. In the first animal (Dog 5165-1), a washer of closed-cell, medical grade, silicone-elastic implant sponge (Becton, Dickinson and Co.) was placed to overly the sensor suture tabs, leaving the arch free. This washer was sutured to the myocardium with 5/0 Mersilene. In the first two procedures (Dogs 5165-1 and -2), each sensor was located with the electrical conductors oriented caudally, while in the last two cases they were located with the conductors oriented cranially. The conductors were formed into a 180-degree bend, in a median plane, for passage through the pericardial incision. (See Figure 5.) The pericardium was then closed with 3/0 silk, including a purse-string suture of 3/0 around the sensor's four electrical conductors. In Dog 5165-4, the pericardium incision directly over the sensor was approximated with three interrupted sutures, leaving open the remaining portion of the incision. Stainless steel sutures were then used to approximate the remaining ribs. Implant sponge, as previously described, was used to fill the void left by rib resection. Wound closure was accomplished in layers, using 0/0 silk interrupted sutures.

An incision was then made dorsally, on the left side, from the implant incision to a location over the vertebral column, between the scapulae. A 2-centimeter-diameter portion of the skin was resected at the terminus to permit fitting of the transcutaneous connector. A purse-string suture of 0/0 silk was used to secure the connector in place. The excess electrical conductors were coiled into the incision which was then closed with 0-silk interrupted-mattress sutures. After recordings were obtained, a plastic snap-on cap was installed on the transcutaneous connector to protect the electrical connector. A stockinette jacket was fitted to the animal to protect the wound.

For hemostasis, a tissue coagulator was used and, while the thorax was open, respiration was maintained by a Phipps-Bird animal respirator. The respirator was connected to the dog via an endotracheal catheter. The blood losses were minimal and the recoveries uneventful in every case. Postoperatively, a course of penicillin therapy was administered to each animal.



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Figure 5. Myocardiographic Strain Gauge Sensor
Implanted on Epicardium

Catheterization

The interpretation of data as novel and complex as the myocardiogram requires simultaneous collection of correlative data from known cardiac activities. For this reason, aortic and left ventricular pressure were chosen in addition to the ECG for postoperative data acquisition. Each animal having a functioning myocardiographic sensor was catheterized twice postimplant to obtain arterial and/or intraventricular pressure data. A total of six catheterizations were accomplished; the first two used the carotid approach, while the last four were made via the femoral artery, as discussed below.

The anesthesia for these procedures was accomplished by administering sodium pentobarbital intraperitoneally. The left inguinal area was shaved, the skin was prepared with bactericidal agents, (Phisohex and benzalkonium chloride) and the area draped.

An incision was made over the femoral-triangle area exposing the femoral artery for a length of 5-centimeters. Loose silk sutures were placed at both ends of the exposed vessel, and a 1- to 2-millimeter axial incision was made midway between sutures. A 90-centimeter ureteral catheter was introduced into the opening and pushed cephalically. If leakage occurred, the proximal suture was tightened around the vessel. As resistance was felt at the aortic semilunar valves, the catheter was carefully



advanced beyond this point for another 2 to 5 centimeters. The cannula was flushed periodically, with a 1:1000 solution of heparin and normal saline, to prevent obstruction by blood coagulation.

After recording and catheter withdrawal, the artery was closed with 5/0 or 6/0 Mersilene sutures. In turn, the wound closure was accomplished in layers, using 0/0 silk.

GROSS PATHOLOGY

Under general anesthesia (sodium pentobarbital) an incision was made parallel to the surgical scar of the implant operation. The scar was healed per primam. The area where the four conductors penetrated the chest wall was avoided, for preservation of tissue, and no inflammatory reaction was noted. On opening the pleural cavity, no exudate was found. The pericardium was adherent to the epicardium for an area of about 15 square centimeters overlying the sensor site. A marginal tag of the left lung was fixed to the thickened pericardium close to the point where the conductors perforated the pericardium. Small atelectatic areas in the otherwise unchanged lung were noticed close to the adhesion. The pericardial sac did not contain any free liquid. After the animal was sacrificed, the sensor assembly was excised—preserving a part of the left ventricle, pericardium, and tissue around the transcutaneous plug for at least 2 centimeters in all directions. After initial fixation, the sensor assembly was removed from the tissue. The pericardium was adherent to the epicardium about the sensor and appeared as a single mass. Fibrotic tissue had completely encased the sensor. The tissue surrounding the sensor was excised by undercutting the sensor and severing the sutures. When the sensor was removed, it was found to be nonadherent to the tissue in which it was enclosed. The sutures holding the sensor fixed to the left ventricle were thought to be placed into an adequate depth and caused only minimal local reaction in the heart muscle. Along the electrical conduits extensive fibrotic changes were noticed in the subcutaneous tissue, especially in the area where the conduits had been coiled.

DATA COLLECTION

A direct-writing oscillograph (Sanborn 850 series) was used to record the data obtained from the animals. Electrocardiographic and myocardiographic information were obtained during the implant procedures. During subsequent recording sessions, blood pressure data were also obtained, via the arterial catheter.

Myocardiograph System

Three outputs from the sensor were available simultaneously by using a bridge-balance box containing three paralleled D-C bridges. The inner



and outer gauges of the sensor were used as one leg of separate bridges, while the third bridge used both gauges as adjacent legs, to provide a summed output. The three outputs, in turn, were used to directly drive the record amplifiers. The recorder preamplifiers were adjusted to accommodate abnormal baseline shifts. Two additional channels of information recorded from the individual gauges were further amplified and recorded on an expanded scale, to facilitate data reduction.

Calibration for these five channels of information was done before and/or after each recording session by balancing the three bridges to the 101-degree-F nominal resistance of the strain gauges. After balancing, the value of the resistance was changed in 10- or 15-ohm steps to plus or minus 150 ohms from nominal.

Electrocardiogram System

ECG potentials obtained during all recording sessions, from needle or safety-pin electrodes, were processed by two means: (1) a back-to-chest bipolar lead configuration was used initially, and (2) a unipolar (V_1) lead was used to provide a more standard recording.

This information was calibrated by 1-mv signals during the recording sessions.

Blood Pressure

A pressure gauge (Model P23Db, Statham Transducers, Inc.) with appropriate fittings, syringe, and catheter was used to obtain blood pressure recordings during the postimplant recording sessions.

This information was recorded on one channel, using the manufacturer's calibration information to reduce the data.



RESULTS

SENSORS

Four sensors were implanted: three were constructed of 0.004-inch, and one of 0.002-inch stainless steel. Sensor No. 3 evidenced an electrical "open" in one strain gauge circuit upon completion of the implant procedure. Sensor No. 1, 0.004-inch, was found to have an electrical "open" at 34 days after implant. The 0.002-inch sensor had developed electrical "opens" in both strain gauge circuits by completion of the implant procedure. This sensor assembly was left in the animal for observations of material acceptability, fluid infiltration, corrosion, and possible reestablished functions.

Recordings made from the implanted sensors were analyzed, using the preimplant calibration as a guide. Each tracing was compared to the calibration information and converted to resistance values, which, in turn, were translated to force values (Table 1).

Table 1. Resistance/Force Characteristics for Implanted Myocardiographic Strain Gauge Sensors

Sensor Number	Recording Day	Strain Gauge Resistance				Compression/Tension From Nominal	
		Ohms					
		Implanted Excursion		Pre-Implant Nominal			
		Grams					
		Inner	Outer	Inner	Outer	Inner	Outer
1	Implant	424.4 401.4	469.9 484.9	426.4	464.9	5 C 20 C	0 9 C
	16	390.4 380.4	458.9 484.9			12 C 33 C	8 T 24 C
	34	436.7 450.4				11 T 25 T	
3	Implant	421 416		423	461.7	2 C 7 C	
	19	409 391				15 C 35 C	
	35	449.3 433				26 T 10 T	
5	Implant	403.4 359.4	464.9 500.9	387.4	464.9	21.5 T 36 C	0 57 C
	12	413.4 383.4	458.4 474.9			35 T 6 C	10 T 18 C
	25	403.4 385.4	473.9 483.9			15 T 2 C	9 C 25 C



In each case, it was determined that the implanted sensors were compressed to some degree—between 7 and 57 grams—at date of surgery. At the approximate two-week test period, the sensors resistance measurements indicated a return toward or through the nominal resistance point. At approximately 30 days, the recordings showed a further shift into the tension range.

PHYSIOLOGICAL DATA

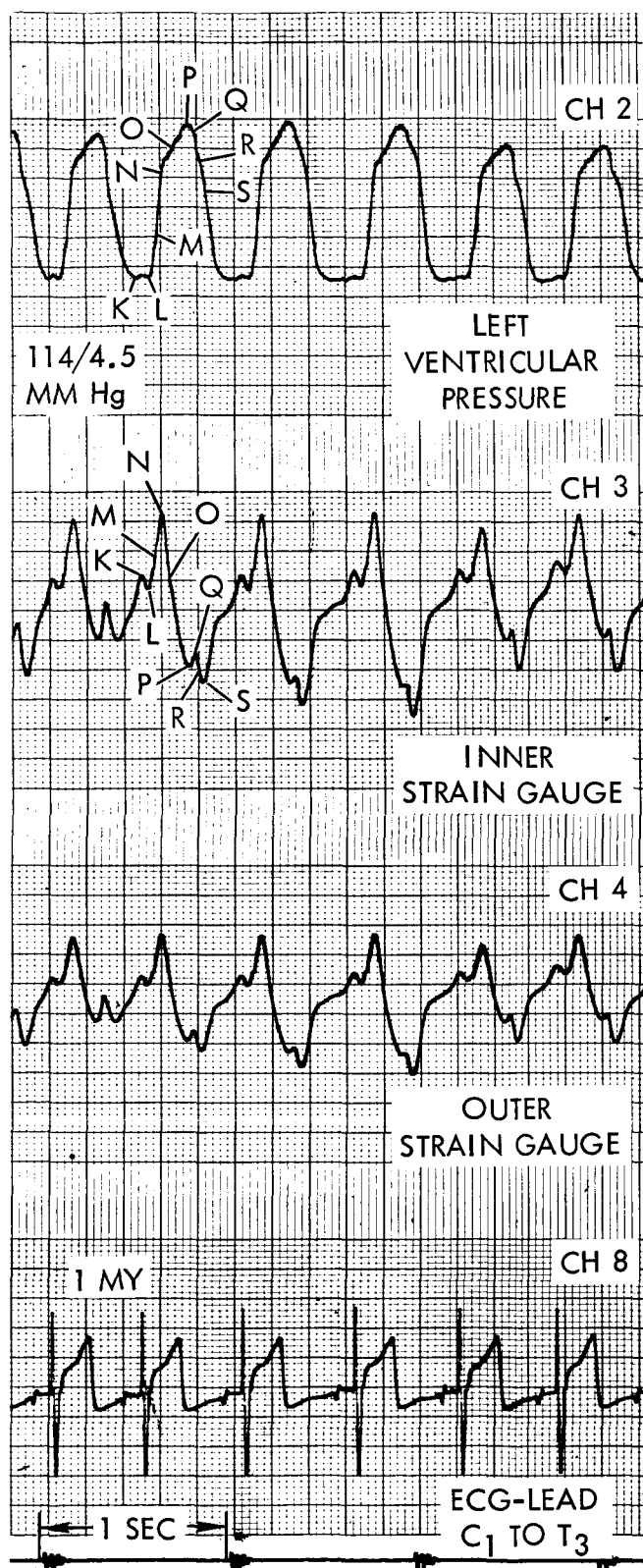
Interpretation of the myocardiogram was facilitated by the simultaneous recording of other cardiac parameters. Initial recordings were made immediately after implantation surgery with only a simultaneous electrocardiogram. The second and third sessions included aortic or left ventricular pressure records. In all cases, the data obtained during any session were uniform and comparable to the other records of that particular animal.

A sampling of the data obtained appears in Figure 6, where the myocardiogram's events are related to those identifiable events of the left ventricular pressure record and the electrocardiogram. The QRS complex of the ECG represents the electrical changes that initiate ventricular contraction and corresponds to the interval just preceding the rapid rise of left ventricular pressure. It should be noted that when the ventricles become smaller, as identified by the ejection phase of the left ventricular pressure record, the myocardiogram shows sensor compression and vice versa. Since the semiconductor strain gauge is a displacement-type transducer, it would be expected that displacing forces due to myocardial contractions and related cardiac volume changes should be measured.

The response of the sensor, then, should be due to a composite of all the forces acting at the site. The sensor is affixed to a small area of myocardium; and, if this were a preparation of isolated tissue only, the displacement or volume changes associated with contractibility of muscle tissue would be noted. Even in such a preparation, since myocardial tissue is a syncytium of fibres (all muscle cells interconnected), the response would be more generalized than with other muscle tissue. Activity of the whole heart, on the other hand, results not only in contraction and relaxation occurring at isolated sites, but in a wave of activity spreading over the entire myocardium, thus causing a displacement of the heart itself as well as local displacement. All these motions will be imparted to the sensor.

Ventricular volume change has been measured by plethysmographic techniques in the past. A comparison of the myocardiogram was made with plethysmographic records displayed by Houssay.¹ The myocardiograph tracings shown in Figure 6 quite closely resemble such volume records. One

¹Houssay, B.A. Human Physiology. New York: McGraw-Hill Book Company, Inc. (1951)

CARDIOVASCULAR
EVENTS

- K-L Atrial Wave
- L-M Entrant Contraction
- M-N Massive Contraction
- L-N Isometric Contraction
- N-O Minimum Ejection
- O-P Maximum Ejection
- P-Q Reduced Ejection
- Q-R Protodiastole
- R-S Isometric Relaxation
- N- Opening of Semi-lunar Valves
- R- Closure of Semi-lunar Valves

Figure 6. Recorded Data: Physiological Interpretation;
Dog 5165-4, 12 Days Postimplant



interesting point is the sharp rise during the period of isometric contraction. This indicates either a response to the local events or to the external myocardium, since there is no change in volume inside the ventricles during this phase. Although the plethysmographic records also show this inflection, it is explained as an artifact due to the technique applied.

Selected recordings from Dogs 5165-1, -2, and -4 are found in the Appendix. Some phase differences are noted in these records. The 34-day sample of Dogs 5165-1 and -4 (Figures A-1 and A-3) are entirely out of phase and dissimilar in appearance; however, if these tracings are inverted, they appear to be correct, a fact which suggests that the signal input was reversed. The phase relations of Dog 5165-2 (Figure A-2) cannot be so simply explained. The appearance of the 34-day records of all dogs differ in similar fashion from the earlier recordings. The recent records appear to be considerably damped, perhaps because of a fibrotic restriction of the sensor.

Before data on Dog 5165-4 were collected at the two-week period, the animal was given two intravenous injections of acetylcholine (0.01 mg/kg) and four of epinephrine (0.1 mg/kg), all at two-minute intervals. This was done to challenge the sensor. Appropriate cardiovascular response was obtained without sensor failure. Subsequent to giving epinephrine, numerous arrhythmias occurred, typified by frequent premature ventricular contractions. Figure 7 displays a portion of this record. The three successive ectopic beats, as identified best by the ECG, show the expected successive decrease in ventricular pressure due to incomplete ventricular filling. The myocardiogram, on the other hand, shows marked irregularity, indicating that the myocardial forces at the site of the strain gauge may be different in each case, that is different initiating foci. Thus the opportunity to observe myocardial response to a variety of stimuli is afforded by the myocardiograph.

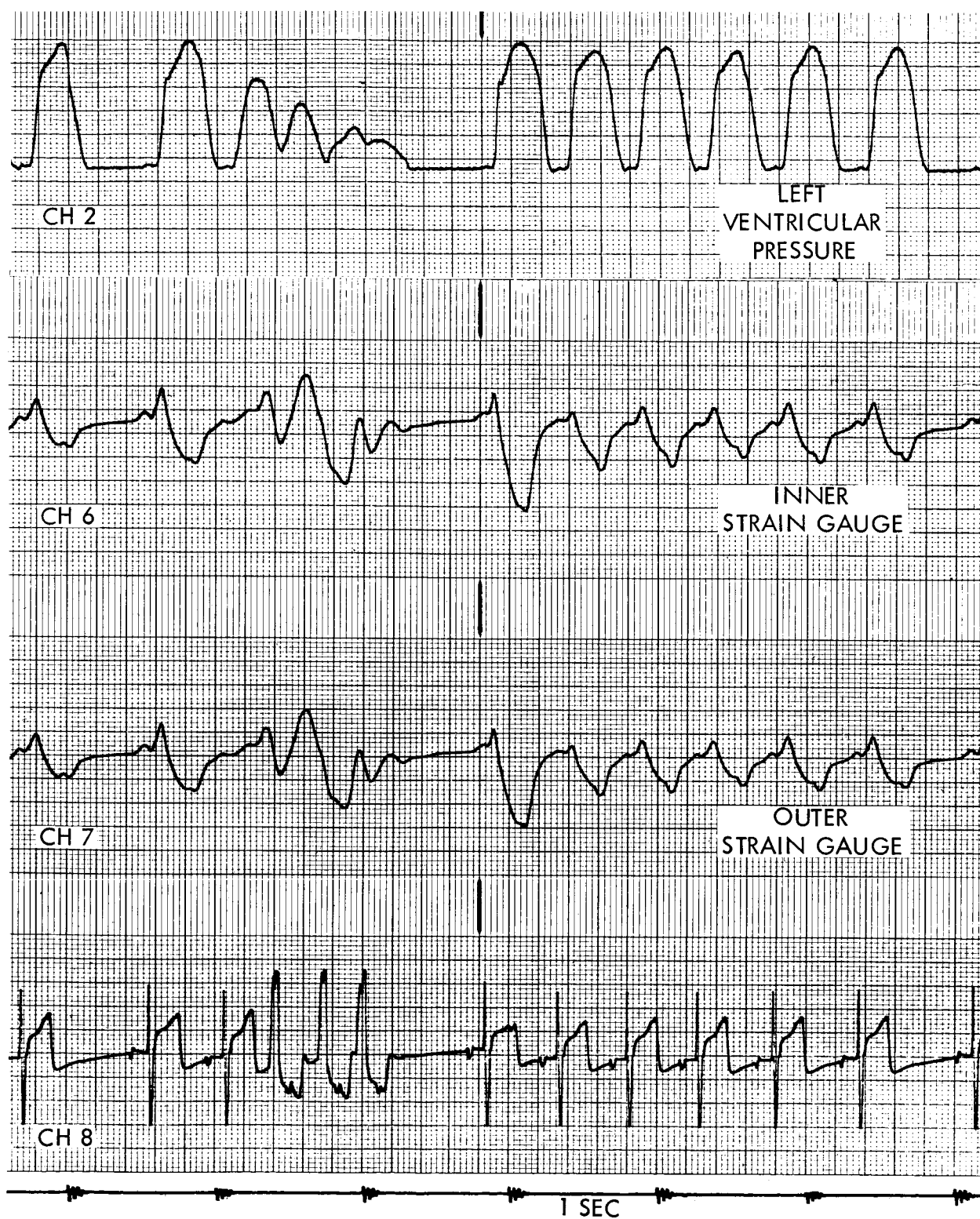


Figure 7. Recorded Data: Chemically-Induced Cardiac Irregularities,
Dog 5165-4, 12 Days Postimplant



CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

This program resulted in the development of an implantable myocardiographic strain gauge sensor assembly capable of an operating life in excess of 30 days. The sensor was of small physical size and did not noticeably compromise the animal's well-being. The transcutaneous connector proved to be biologically acceptable.

Sensors of this design and configuration constructed of 0.004-inch stainless steel and processed as reported, appear to provide a reasonable strain level for the strain gauges used. While a like device constructed of 0.002-inch material creates a high strain level resulting in failure of the strain gauges.

A considerable amount of data was collected regarding the activity of this sensor when attached to the heart. Inasmuch as this program called for a qualitative rather than quantitative data analysis, only assumptions can be made as to the exact meaning of the information gathered.

Certain discrepancies in sensor response were noted during this research effort:

1. There is less than optimum correlation between the forces measured by the two individual gauges on a given sensor. This could occur as a result of any of several events, the primary one being a possible twisting motion of the sensor during contraction of the ventricles.
2. Sensor response appears to become damped by the final recordings. This distortion of information could be caused by fibrotic tissue growth changing the physical response of the sensor and/or the sensor being forced into contact with other anatomical structures after implant and during the healing process. A difference in the appearance of the record could also occur with changing animal position.
3. Postimplant calibrations showed significant shifts over preimplant data.



Any or all of the previously mentioned actions could cause several force vectors that could distort gauge response so that readings might be obtained that are at variance with preimplant calibration data. Those differences indicating distention or compression of the gauges could create the variations in data that were noted.

Direct measurement of myocardial activity is not a simple task, especially for the continuous monitoring of a healthy animal. Plethysmographic techniques are obviously not physiologic, and other techniques are not amenable to continuous recording. Analyses to date indicate that the myocardiogram can be interpreted as a measure of ventricular volume change and, more specifically, a vector sum of forces occurring at the site of the sensor. Thus, this device could become a useful tool for the study of myocardial function.

RECOMMENDATIONS

The qualitative analysis of the data obtained during the term of this contract does not provide a sufficient basis for reaching positive conclusions regarding the complete usefulness of the myocardiographic strain gauge sensor. It appears, however, from the relationship of the myocardiogram to ECG and left ventricular pressure, that there is in some cases a direct relationship between strain gauge output and cardiovascular activities, especially ventricular volume changes.

It is recommended that a qualitative study be undertaken to permit additional sensor and data analysis. This study should include further research on the activity and effects of this particular sensor design, and the feasibility of providing reproducible records that can be correlated with cardiovascular events.

This device appears to offer promise as a physiological research tool, and it may prove useful in validating other sensor systems, such as external vibrocardiogram sensors.

In order to understand more completely the information provided by the myocardiogram and to make it a practical research tool, several further studies should be undertaken. They are:

1. Extensive analysis of data collected during this program
2. Multiple implants of a number of sensors at different sites in each animal



3. Development of surgical procedures to compare plethysmographic ventricular volume with myocardial data in the same animal
4. Obtain sensor data from isolated myocardial tissue sections.

When the myocardiograph is validated, studies can be initiated to shed light on certain myocardial responses of great clinical interest that were previously evaluated only indirectly, such as:

1. The effect of changes in ion concentration, especially potassium, upon myocardial function
2. The myocardial response of a subject to toxic concentrations of digitalis.



APPENDIX

RECORDED DATA

Recorded data derived from the surgical implants during this program are presented in Figures A-1, A-2, and A-3.

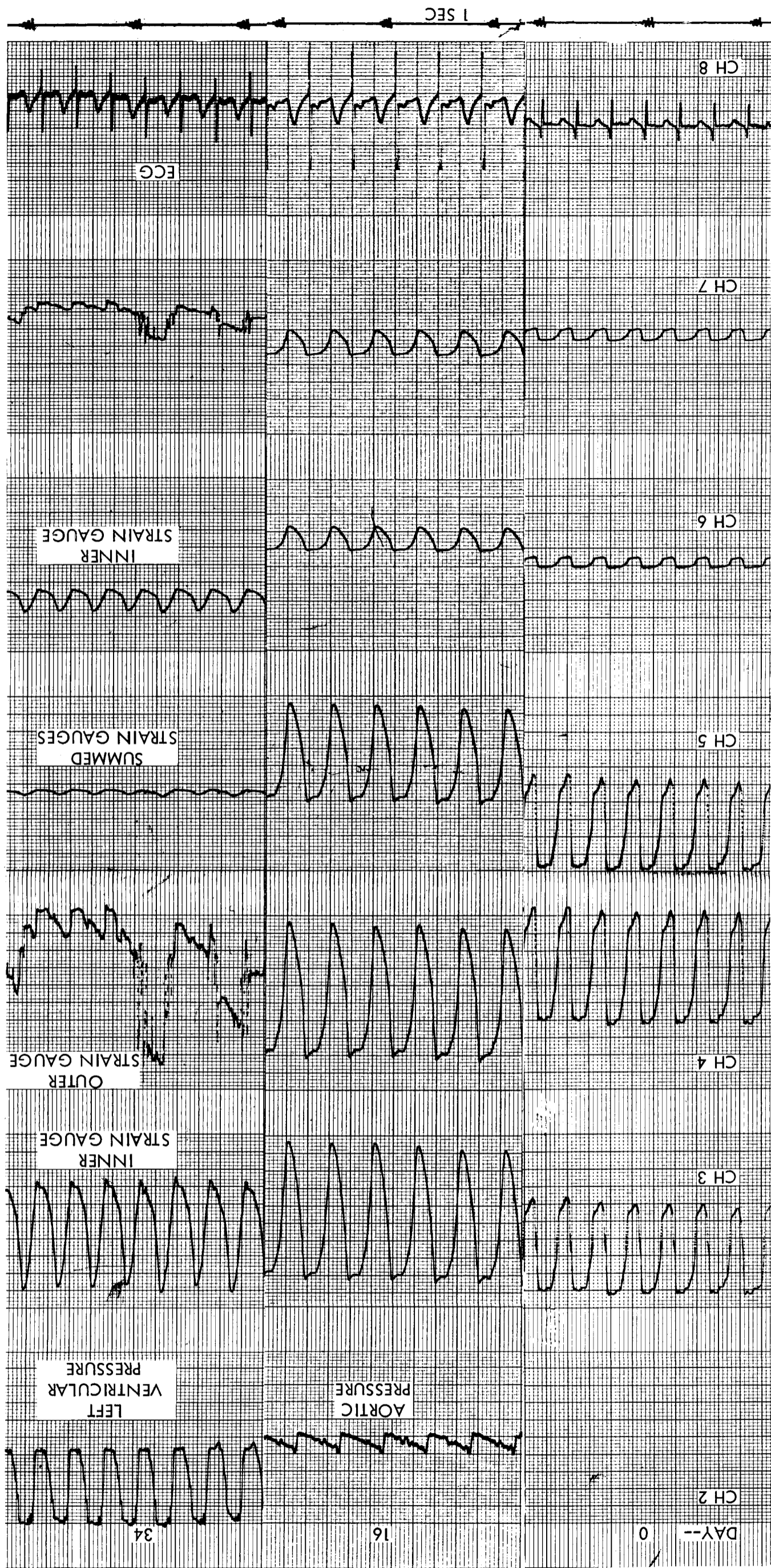


Figure A-1. Recorded Data: Dog 5165-1

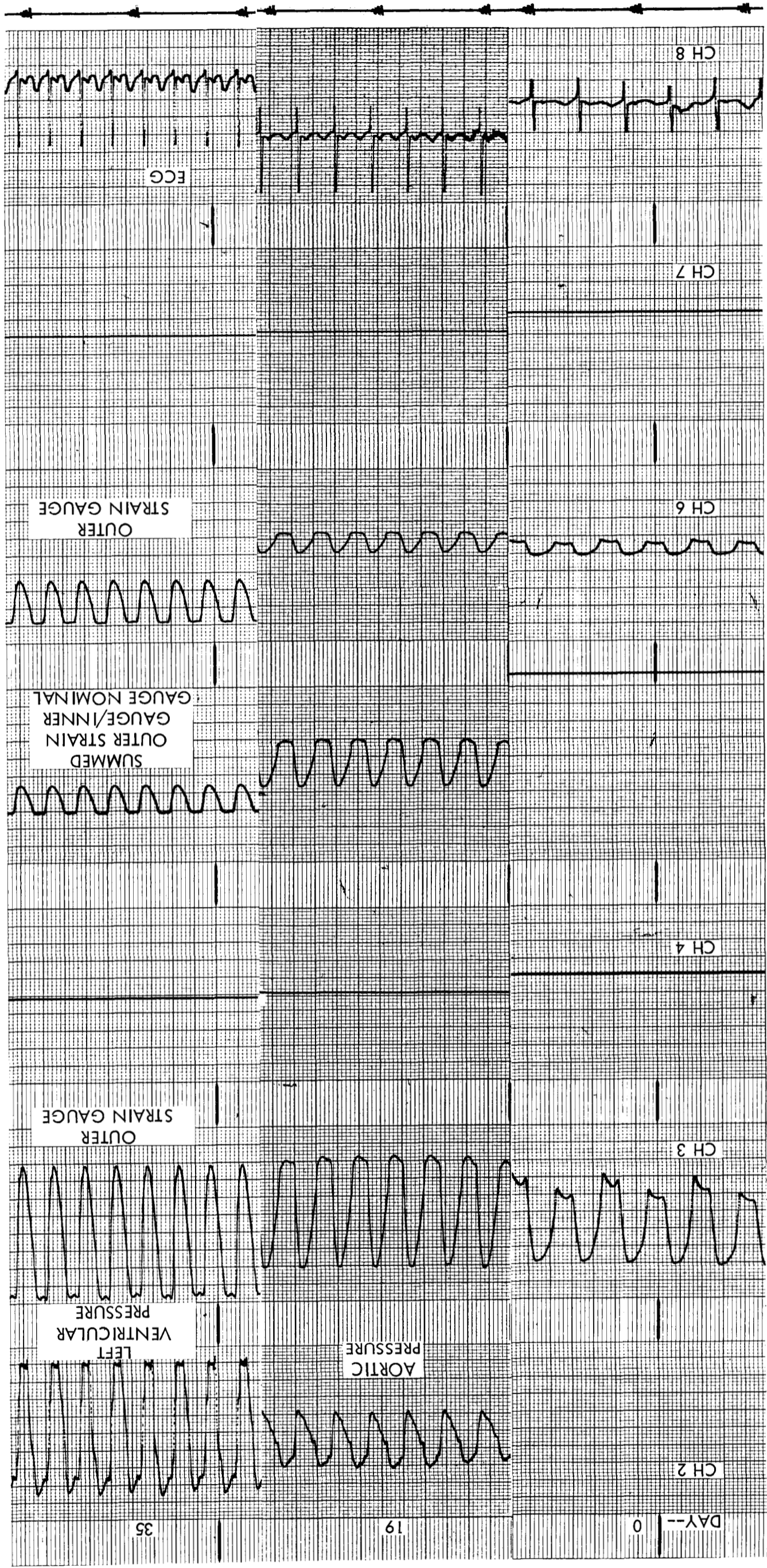


Figure A-2. Recorded Data: Dog 5165-2

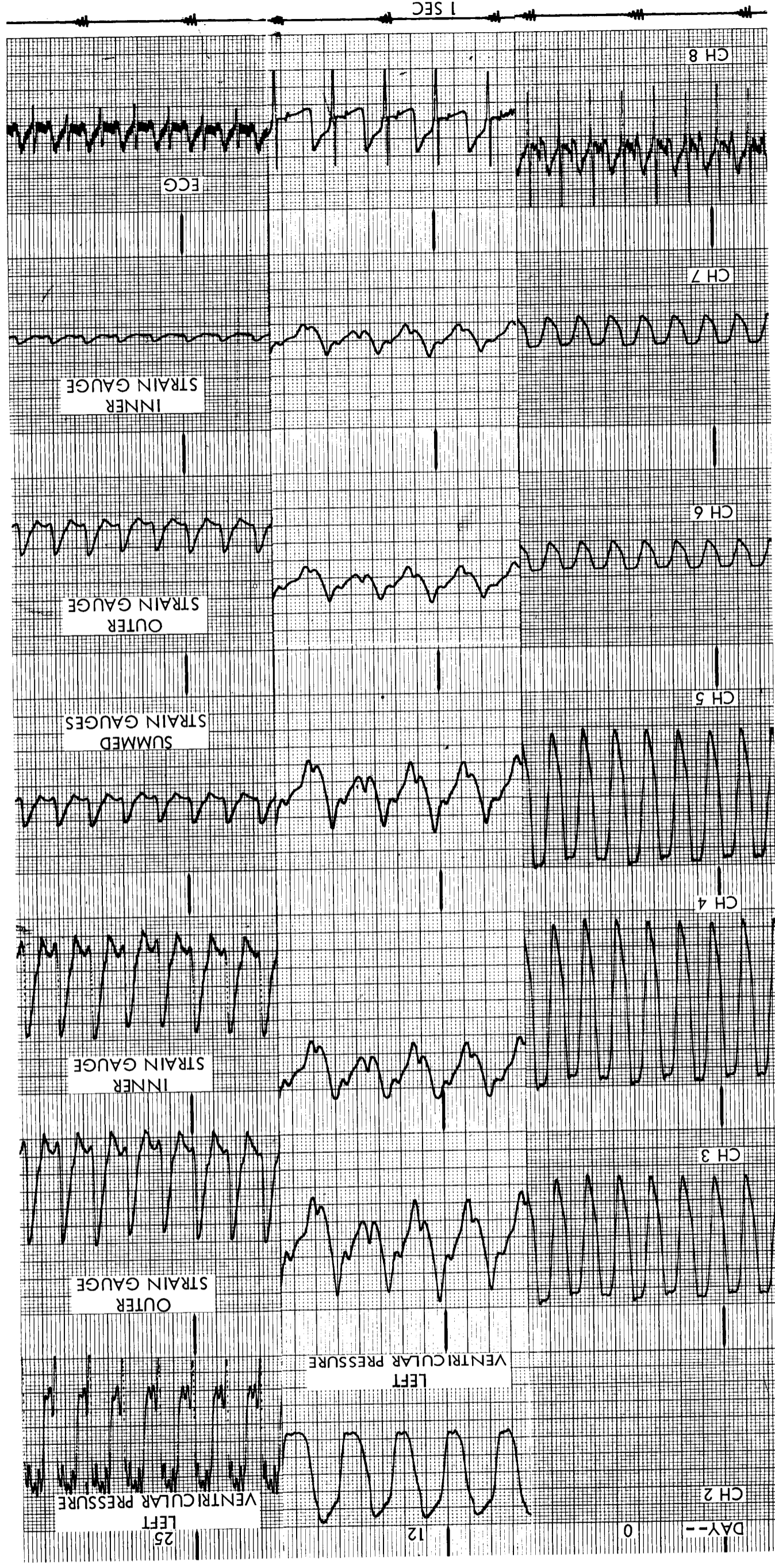
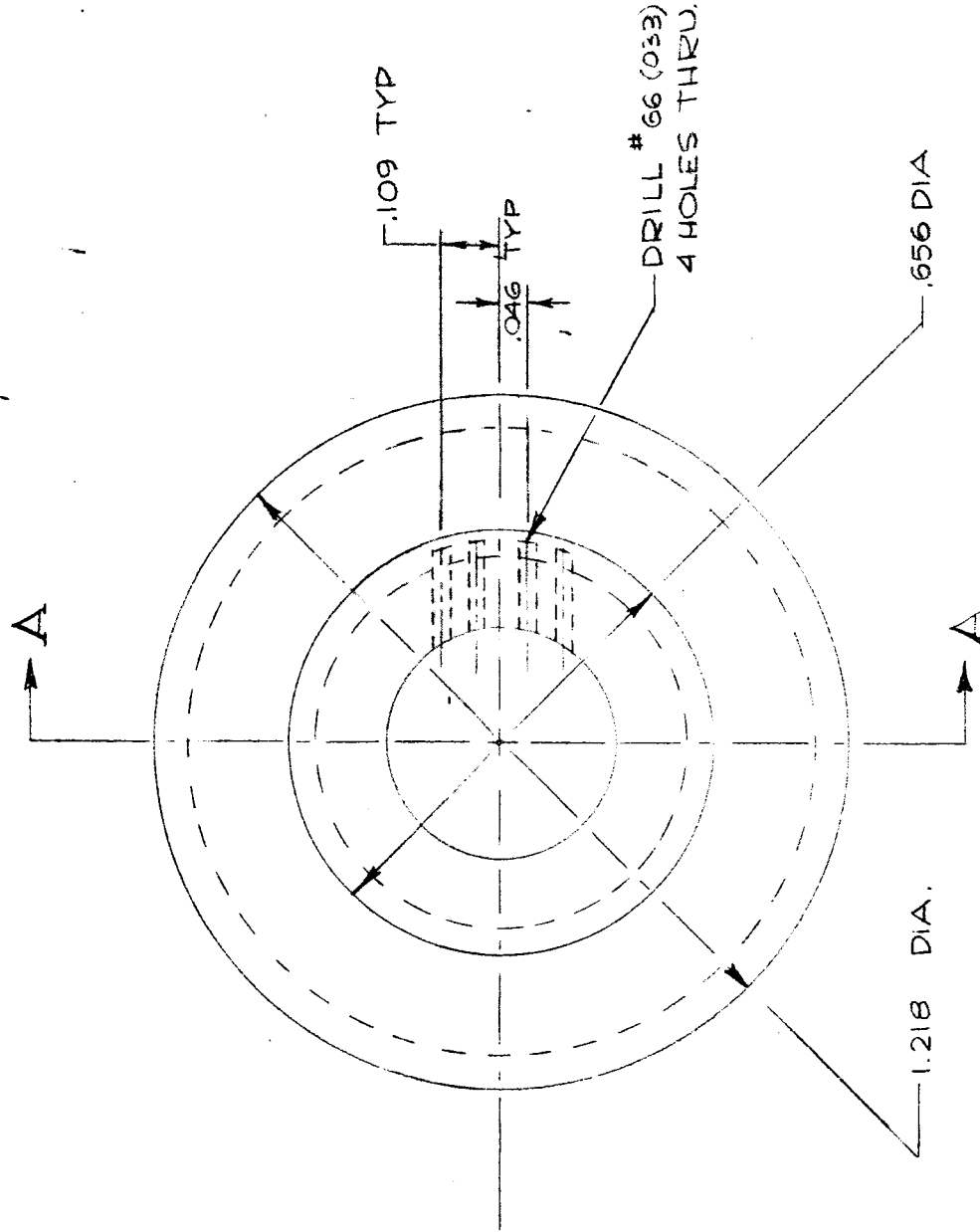


Figure A-3. Recorded Data: Dog 5165-4



— BREAK ALL
SHARP EDGES

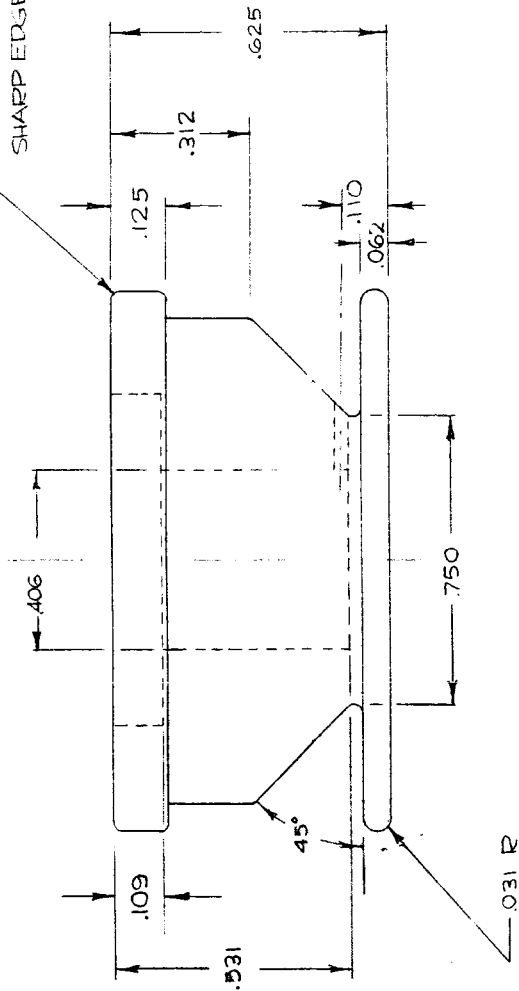
REVISIONS

SYM	DESCRIPTION	DATE	APPROVED
	1. MAY BE REWORKED 2. CANNOT BE REWORKED 3. RECORD CHANGE 4. NOW SHOP PRACTICE 5. PARTS MADE OK		

N64-32890

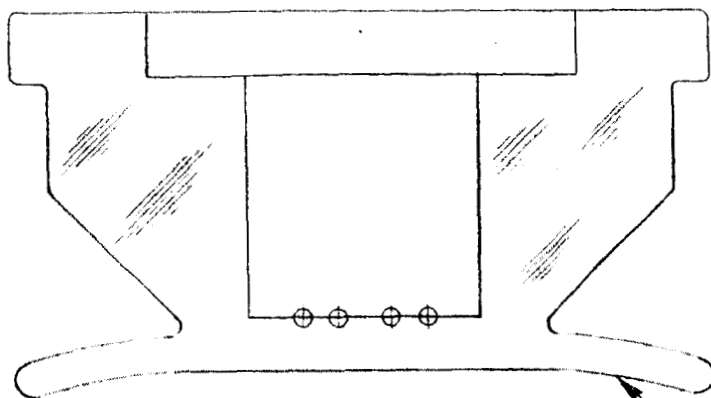
020

BREAK ALL
SHARP EDGES



5. POT THE ELECTRICAL INSERT INTO THE TRANSISTOR CONNECTOR WITH DEGASSED POLYURETHANE CS 3502, CHEMSEAL CORP. OF AMERICA. CURE 6 HRS. @ 180° F.
4. APPLY PRIMER CS 9937 CHEMSEAL CORP. OF AMERICA TO AREAS CALLED OUT IN NOTE #3. AIR DRY UNTIL 'TACK' FREE.
3. REMOVE THE FLUX & DEGREASE THE OUTSIDE DIA. & BOTTOM OF ELECTRICAL INSERT WITH TRICHLOROETHYLENE IN ADDITION TO THE INTERIOR OF THE .406 HOLE.
2. SOLDER -13 TO ELECTRICAL SOCKETS
1. PASS GO 5165-1 -13 CABLES THRU #6 HOLES & LIGHTLY SAND INSULATION FOR 1/4 INCH

NOTES: UNLESS OTHERWISE SPECIFIED



VIEW-AA

HEAT & BEND TO
DESIRED CONTOUR

ISSUE CONNECTOR
HEMSEAL CORP.

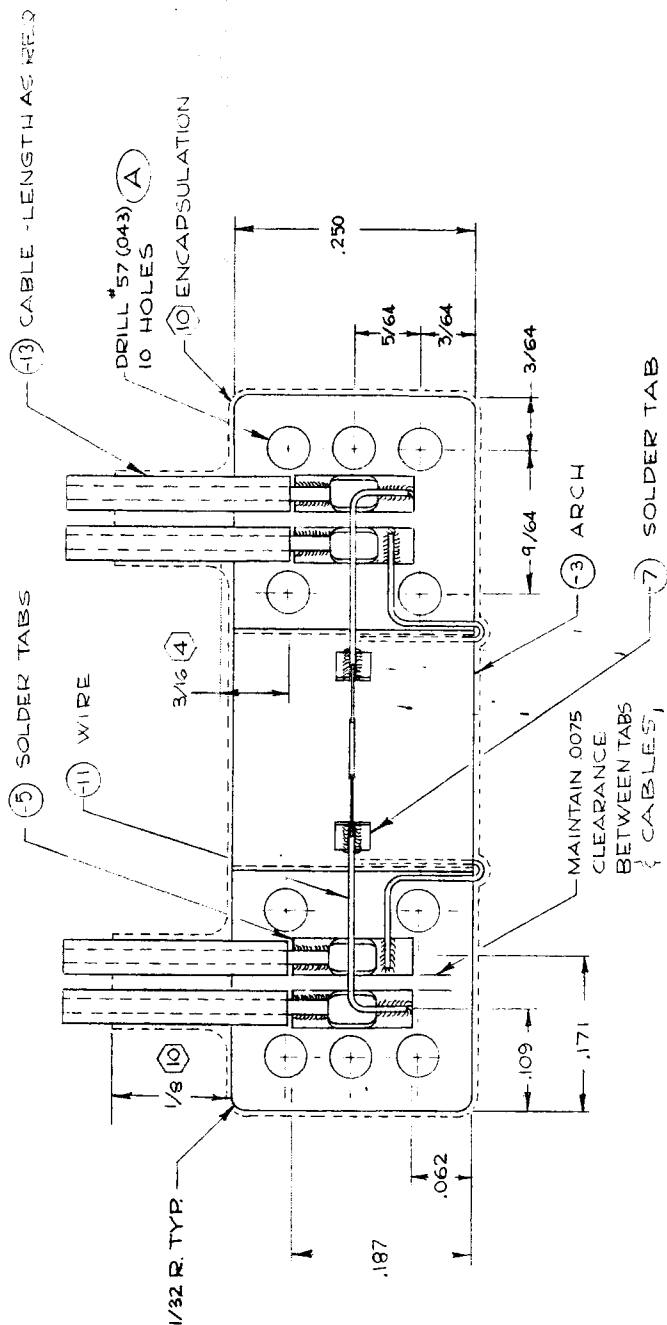
RP. OF AMERICA
Y UNTIL "TACK" FREE.

IA & BOTTOM OF
IN ADDITION

HTLY SAND INSULATION

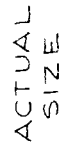
ITEM	QTY	MODEL	NEXT USING DRAWING	END ITEM NO.	THRU
REQD PER END ITEM				EFFECTIVE ON	
APPLICATION (USAGE) DATA					







⑩ ENCAPSULATION



TAB

REVIEWS

SYM	DESCRIPTION	DATE	APPROVED
	1. MAY BE REWORKED 2. CANNOT BE REWORKED 3. RECORD CHANGE 4. NOW SHOP PRACTICE 5. PARTS MADE OK		
A	1. DRILL # 57 (043) WAS DRILL # 61 (039)	6/13/64	CWH

[illegible]

		018	←
		017	
		016	
		015	
		014	
		013	
		012	
		011	
		010	I I
		009	
		008	
PLASTIC	1.218 DIA X 625 PLEXIGLASS - NAA	007	
	# 28 GAUGE 16/40 3006-2816 PE CALMONT WIRE CO. SANTA ANA	006	
NYCLAD	# 36 NYCLAD	005	
	MODEL 110001-001 500 OHMS ±15% MICRO SYS. PASADENA	004	
COPPER CLD. FIBERGLASS	062 X 062 MICRO SYS. PASADENA	003	I I
COPPER CLD FIBERGLASS	031 X .125 MICRO SYS. PASADENA	002	
CRES 17-7 PH	.002-.003-.004 X .250 X .750	001	
MATERIAL	DATA: SPECIFICATION SIZES, NOTES, SUPPLIERS	LINE NO.	

TS LIST

NORTH AMERICAN AVIATION, INC.
SPACE and INFORMATION SYSTEMS DIVISION
12214 LAKEWOOD BLVD., DOWNEY, CALIFORNIA

SENSOR MYOCARDIOGRAPHIC STRAIN GAUGE

CODE IDENT NO.

03953

SIZE

D

GO 5165-1

SCALE 10 X

SHEET 1 OF 1